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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,316	05/15/2001	Jacqueline Sharon	701586-46074 DIV 2	9999

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/855,316	<b>Applicant(s)</b> SHARON, JACQUELINE	
	<b>Examiner</b> Christopher H Yaen	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 111,112,114-121 and 123-136 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 111,112,114-116,118-121 and 123-136 is/are rejected.
- 7) ☒ Claim(s) 117 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Re: Sharon J.**  
**Priority Date: 31 January 1994**

1. The amendment filed 7/30/2004 is acknowledged and entered into the record. Accordingly, claims 1-110, 113, and 122 are canceled without prejudice or disclaimer, and claims 132-136 are newly added.
2. Claims 111-112, 114-121, 123-136 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Maintained - 35 USC § 102***

4. The rejection of claims 111-112, 114-116, 118, 120-121, 126-131, and now newly added claims 132, and 134-135 as being anticipated by Gram *et al* (PNAS USA 1992; 89:3576-3580) under 35 USC § 102(b) is maintained for the reasons of record. Applicant argues that the reference fails to teach in-mass transfer as disclosed in the instant invention. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The claims as currently interpreted are drawn to a composition comprising a library of expression vectors that contain nucleic acids that encode variable regions. Because the claimed invention is drawn to a product *per se*, the means by which the library of expression vectors encoding variable regions are made is irrelevant. As such, Gram *et al* teach a library of expression vectors that comprise nucleic acids that encode variable regions (see abstract). The patentability of a product does not depend on its method of production.

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If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Thus applicant’s arguments are not persuasive and the rejection is maintained.

***Claim Rejections Maintained - 35 USC § 103***

5. The rejection of claims 111-112, 114-116, 118-121, 123-131, and now newly added claims 132-136 as being obvious over Gram *et al* in view of Bender *et al* (Hum. Antibod. Hybridomas, 1993; 4:74-79) under 35 USC § 103(a) is maintained for the reasons of record. Applicant’s arguments are substantially similar to those previously argued for the Gram *et al* reference. Applicant additionally argues that the references teach away from one another because Gram *et al* teach antibody fragments, while Bender *et al* teach whole antibodies. Applicant’s arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Absent any unexpected results, the claims of the instant invention are currently interpreted as a composition comprising a library of expression vectors that encode variable regions. One of ordinary skill in the art have reasonable expectation in combining the references because both the composition comprising the library of expression vectors and a vector comprising full length antibodies as taught by Bender *et al* were already known and readily practiced in the art by the ordinary artisan. The combination of the two references would result in the expression of a diverse array of full length antibodies without the need to utilize the conventional method of generating antibodies. One of

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skill in the art would have been motivated to do so because Gram *et al* states that their method of in vitro affinity maturation would be capable of generating diverse antibody chain repertoires that cannot be generated by normal immunization techniques (see page 3580, last paragraph). The expectation lies in the fact that both Gram *et al* and Bender *et al* both teach libraries of expression vectors that are capable of recognizing specific antigens. Thus applicant's arguments are not persuasive and the rejection is maintained.

### ***Conclusion***

**No claim is allowed.**

**Claim 117 is objected to for being dependent on a rejected claim.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
October 17, 2004



**GARY NICKOL**  
**PRIMARY EXAMINER**